

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9016

Bartle, J.

February 18, 2013

Marilynn L. Scott ("Ms. Scott" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Kirsten I. Bucher, Ms. Scott's child, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has attested to at least 45 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated March 20, 1998, Dr. Notske attested in Part II of Ms. Scott's Green Form that she suffered from moderate mitral regurgitation, mitral annular

3. (...continued)

contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

calcification,⁴ and an abnormal left atrial dimension.⁵ Based on such findings, claimant would be entitled to Matrix B-1, Level II benefits in the amount of \$41,589.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Angelo S. Ferraro, M.D., F.A.C.C., stated in the "IMPRESSIONS" section that claimant had "[m]ild ... mitral regurgitation," but in another section of the report he noted that claimant had "at least [moderate mitral regurgitation] (poor flow signals)." Dr. Ferraro, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Ferraro also commented that claimant had a "dilated left atrium" with a superior-inferior systolic dimension of

4. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

5. Dr. Notske also attested that claimant suffered from moderate aortic regurgitation, aortic sclerosis, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors delineated in the Settlement Agreement.

between 5.7 and 6.0 cm and an antero-posterior systolic dimension of 4.7 cm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id.

§ IV.B.2.c.(2)(b).

In July, 2005, the Trust forwarded the claim for review by Issam A. Mikati, M.D., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had moderate mitral regurgitation and stated that "[mitral regurgitation] is mild." Dr. Mikati also determined that there was no reasonable medical basis for Dr. Notske's finding that claimant had an abnormal left atrial dimension because the "[m]easurement on [the] tape encroached on [the] mitral annular plane."

Based on Dr. Mikati's findings, the Trust issued a post-audit determination denying Ms. Scott's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted declarations from Dr. Notske and

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Scott's claim.

Dr. Ferraro. In his declaration, Dr. Notske stated with respect to the level of Ms. Scott's mitral regurgitation:

The mosaic jet of mitral regurgitation is obvious in numerous views. In the left parasternal view, for example, the jet takes up nearly 40% of the area of the left atrium. This three dimensional jet, when seen in the "measuring view" of the apical four chamber, not only encompasses at least one-third of the area of the left atrium, but also extends along the Atrial Septum to nearly reach the back wall of the Atrium. Thus, it easily meets the criteria for moderate mitral regurgitation under the standards set forth in the AHP Settlement Agreement. I am not aware of any contrary finding by the auditing cardiologist and his finding of mild mitral regurgitation is not supported and is without any reasonable medical basis.⁸

In his declaration, Dr. Ferraro stated that:

I have reviewed the comments of the auditing cardiologist regarding the March 20, 1998, echocardiogram and have re-reviewed the March 20, 1998, echocardiogram videotape. Following my review of the March 20, 1998, echocardiogram videotape, my professional opinion is that this echocardiogram demonstrates that Ms. Scott has moderate mitral regurgitation equal to or exceeding 20% RJA/LAA.

Ms. Scott argued that Dr. Ferraro's declaration "clarifies that in his initial interpretation of the echocardiogram where he referred to the severity of the mitral valve as mild he was

8. Dr. Notske also reaffirmed his determination that Ms. Scott had an abnormal left atrial dimension. In addition, he asserted that claimant had a reduced ejection fraction in the range of 50% to 60%, which is another complicating factor delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b)iv). Given our disposition with regard to the level of claimant's mitral regurgitation, we need not resolve these issues.

interpreting the echocardiogram as a clinical cardiologist, not for purposes of the AHP Settlement Trust." In addition, claimant contended that the Trust should accept Dr. Ferraro's opinion because he previously had audited echocardiograms for the Trust.

The Trust then issued a final post-audit determination, again denying Ms. Scott's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO NO. 2807, Audit Rule 18(c). The Trust then applied to the Court for issuance of an Order to show cause why Ms. Scott's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 11, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the Court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Scott had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Scott argues that her attesting physician's Green Form representation that she had moderate mitral regurgitation is supported by a reasonable medical basis because two "highly qualified, well-respected cardiologists" concur. Claimant also asserts that Dr. Notske responds specifically and directly to the auditing cardiologist's findings while the auditing cardiologist only says that "[mitral

regurgitation] is mild." Claimant further contends that Dr. Ferraro's statement in his declaration that Ms. Scott had moderate mitral regurgitation is not inconsistent with the observations recorded in the echocardiogram report because in the report he stated there that the mitral regurgitation was at least moderate and the conclusions in the echocardiogram report were drawn for clinical purposes. Finally, claimant submitted a supplemental declaration of Dr. Notske to respond to the Trust's suggestion that his opinion is not entitled to as much weight because of the number of Green Forms he has completed.

In response, the Trust argues that claimant's supplemental declarations fail to establish a reasonable medical basis for Dr. Notske's representation that Ms. Scott had moderate mitral regurgitation. In addition, the Trust argues that Dr. Ferraro did not, despite the opportunity to do so in his declaration, offer any explanation as to why he indicated twice in the echocardiogram report that the echocardiogram demonstrated mild mitral regurgitation.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson stated:

The quality of this echocardiogram is suboptimal. The technologist used a variance color map which is not a standard color processing used in adult cardiology. This is not the color processing used by Singh or

Helmcke in the original articles. Also, the technologist zoomed in on the mitral regurgitant jet whenever it appeared in the apical views, concurrently cutting off part of the left atrial chamber. Thus, you cannot estimate RJA/LAA in the apical views because it is impossible to see the entire left atrium simultaneously with the mitral regurgitant jet. The mitral regurgitation appears mild in the parasternal long axis. When calculating the RJA/LAA ratios, you must use the left atrial area obtained in the apical 4 chamber before magnification is applied. Despite the difficulties with the measurements, I planimetered three mitral regurgitant jets and calculated the RJA/LAA ratios using a left atrial area of 21.6 cm obtained in the apical 4 chamber view. My measurements for mitral regurgitant jet area/left atrial area are $2.8 \text{ cm}^2/21.6 \text{ cm}^2$, $3.7 \text{ cm}^2/21.6 \text{ cm}^2$ and $3.4 \text{ cm}^2/21.6 \text{ cm}^2$. These ratios are 13%, 17%, and 16%, all of which are less than 20%, and are consistent with mild mitral regurgitation.

....

In summary, this Claimant has mild mitral regurgitation with an abnormal left atrial dimension. There is no reasonable medical basis for the Attesting Physician's claim that Marilynn Scott has moderate mitral regurgitation.

In response to the Technical Advisor Report, claimant argues the Technical Advisor did not show how Dr. Notske or Dr. Ferraro violated the principles and methods of Feigenbaum or Weyman. Claimant also contends the Technical Advisor did not consider all the information Ms. Scott submitted, including the declaration of Dr. Ferraro. In addition, claimant argues that the suboptimal quality of her echocardiogram does not lend credence to the Trust's position as to the severity of the regurgitation. Finally, claimant states that the Technical

Advisor did not disclose which of Feigenbaum's measuring protocols she used and therefore must not have used Feigenbaum's "most common approach," which requires measurement of the entire mitral regurgitant jet including surrounding, lower flow spray.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Contrary to claimant's contention, the opinions of Dr. Notske and Dr. Ferraro do not provide a reasonable medical basis for the attesting physician's Green Form representation that Ms. Scott had moderate mitral regurgitation. As an initial matter, Dr. Ferraro initially concluded that claimant's echocardiogram demonstrated only mild mitral regurgitation, noting it twice in his report. Although Dr. Ferraro later stated that the same echocardiogram shows moderate mitral regurgitation, Dr. Ferraro does not even attempt to explain the discrepancy with his earlier conclusion.

In addition, the Technical Advisor reviewed claimant's echocardiogram and determined it showed only mild mitral regurgitation. Specifically, Dr. Abramson noted that the study was suboptimal because the sonographer used a non-standard color process and magnified the mitral regurgitant jet. Notably, Dr. Ferraro also observed the limited nature of the study, noting that his review of claimant's mitral regurgitation was impaired because of "poor flow signals." Notwithstanding these limitations, Dr. Abramson was able to measure the level of claimant's regurgitation to be 13%, 16%, and 17%, all of which

are significantly below the 20% threshold established in the Settlement Agreement.

We further reject claimant's argument that the Technical Advisor failed to rebut Dr. Notske's specific measurements. Although Dr. Notske attested that the regurgitant jet occupied at least one third of the left atrium in the apical four chamber view, Dr. Abramson observed that the technologist zoomed in on the mitral regurgitant jet when it appeared in the apical views, cutting off part of the left atrial chamber and rendering accurate RJA/LAA estimates in this view impossible to obtain. For purposes of establishing moderate mitral regurgitation, the Settlement Agreement requires measurements from the apical views. See Settlement Agreement § I.22. Thus, contrary to claimant's argument, the Technical Advisor specifically identified deficiencies in the echocardiogram on which the attesting physician relied in making his Green Form representation of moderate mitral regurgitation.

Finally, we reject claimant's argument that the Technical Advisor Report is deficient because it fails to expressly state the Technical Advisor's methods. Dr. Abramson reached her conclusion that the attesting physician's Green Form representation was not supported by a reasonable medical basis by performing her own measurements as well as by identifying the deficiencies in the echocardiogram that affect evaluation of mitral regurgitation. Dr. Abramson explained that she arrived at her measurements by planimetering three regurgitant jets and

using the left atrial area obtained in an apical view before magnification. Moreover, Dr. Abramson stated "My review of this Claimant's Record was performed in accordance with the standards set forth in the Green Form and in the Nationwide Class Action Settlement Agreement with American Home Products Corporation."¹⁰

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Scott's claim for Matrix Benefits and the related derivative claim submitted by her child.

10. For this reason as well, we also disagree with claimant that Dr. Abramson did not consider all of the information Ms. Scott submitted.